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EXAMINER	
EPPERSON, JON D	
ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 09/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
F/C Cy	10/034,212	GILON, CHAIM	
	Examiner	Art Unit	
	Jon D Epperson	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-34 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-34 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Please note: The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to **Group Art Unit 1639**.

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-11 and 20, drawn to a product described as a "scaffold-based compound", classified variously depending on the "ring" structure in, for example, class 544, subclass 1, 63.

II. Claims 12-15, drawn to a product described as a "library", classified variously in class 435, subclass 6, DIG 22, DIG 34.

III. Claims 16-19 and 21, drawn to a product described as a "pharmaceutical composition", classified variously in class 424, subclass 464+, 455.

IV. Claim 22, drawn to a method of "modulating" protein or peptide-mediated cell activity, classified variously depending on the structure of the compound and the identity of the cell mediated activity, for example, class 424, subclass 93.1+.

V. Claims 23-24, drawn to a method for "treatment of a disease", classified variously depending on the structure of the compound, for example, class 544, subclass 313.

VI. Claims 25, 27-29, drawn to a method for "identifying a candidate which modulates a protein or peptide-mediated cell activity", classified variously in class 435, 6, DIG 2.

VII. Claim 26, drawn to a method of "screening on a computer", classified variously in class 435, subclass 6, DIG 20.

VIII. Claim 30, drawn to a product described as a "modulator" obtained by the method of claim 28", classified variously depending on the structure of the modulator, for example, class 544, subclass 1, 63.

IX. Claim 31, drawn to a method described as "a method for modulating a protein or peptide-mediated cell activity ... with a modulator obtained by the method of claim 28", classified variously depending on the structure of the modulator and the nature of the activity, for example, class 544, subclass 1, 63.

X. Claims 32-34, drawn to a product described as a marker linked compound, classified variously depending on the structure of the marker linked compound, for example, class 544, subclass 1, 63.

Additional "Ring" Structure Election Requirement Applicable to All Groups:

2. In addition, each Group detailed above reads on patentably distinct "ring" structures. Each "ring" structure is patentably distinct because they are unrelated i.e., the compounds do not share a common core structure and/or activity. Therefore, these compounds have different issues regarding patentability and enablement, and represent patentably distinct subject matter, which merits separate and burdensome searches (they are also classified in different classes and subclasses depending on their structures). Art anticipating or rendering obvious each of the above-identified "ring" structures would not necessarily anticipate or render obvious another "ring" structure, because they are drawn to different inventions that have different distinguishing

features and, as a result, a further restriction is applied to the above Groups. For an elected Group, Applicant(s) **must elect** a single "ring" structure e.g., applicant must specify X, Y, B, Z, A, W, m and n (i.e., all of the "ring" atoms need to be specified). It is noted that this is a restriction requirement to a single "ring structure" and **NOT** a species election requirement.

3. The inventions are distinct, each from the other because of the following reasons:

4. Groups I-X represent separate and patentably distinct inventions. Groups IV-VII and IX are drawn to different methods and Groups I-III, VIII and X are drawn to different products (i.e., e.g., which are directed to different purposes, use different materials, recite different method or process steps for the preparation of different product(s), screening of different characteristics, such as different binding affinities, different biochemical reaction conditions, etc. or lead to different final results). Therefore, the groups that describe these products and methods have different issues regarding patentability and enablement, and represent patentably distinct subject matter, which merits separate and burdensome searches. Art anticipating or rendering obvious each of the above-identified groups respectively would not necessarily anticipate or render obvious another group, because they are drawn to different inventions that have different distinguishing features.

5. Groups I-III, VIII and X represent patentably distinct products. Groups I-III, VIII and X represent separate and patentably distinct products because they differ in respect to their properties, their use and the synthetic methodology for making them. For example, Group X is drawn to a "marker linked", which requires different reagents and/or materials than Groups I-III

and VIII (i.e., requires a "marker"). Likewise, Group VIII is drawn to a "modulator", which requires different reagents and/or materials than Groups I-III and X (i.e., requires the materials produced by the method of claim 28). Likewise, Group III is drawn to a "pharmaceutical composition", which requires different reagents and/or materials than Groups I-II, VIII and X (i.e., materials for pharmaceutical compositions). In addition, Group II is drawn to a "", which requires different reagents and/or materials than Groups I, III, VIII and X (i.e., a "library" of compounds. Therefore, art anticipating or rendering obvious each of the above-identified groups respectively would not necessarily anticipate or render obvious another group, because they are drawn to different inventions that have different distinguishing features and/or characteristics. Consequently, Groups I-III, VIII and X have different issues regarding patentability and enablement and represent patentably distinct subject matter.

6. Groups IV-VII and IX represent separate and patentably distinct methods (and the corresponding products made by those patentably distinct methods). The methods are distinct because they use different steps, require different reagents and/or will produce different results. In the instant case, Group IX requires the use of a "modulator obtained by the method of claim 28", which is a step that is not required by the methods of Groups IV-VII. Group VII requires "screening on a computer", which is a step that is not required by the methods of Groups IV-VI and IX. Group VI requires steps for "identifying a candidate which modulates a protein or peptide-mediated cell activity", which is a step that is not required by the methods of Groups IV-V, VII and IX. Group V requires "treatment of a disease", which is a step that is not required by the methods of Groups IV, VI-VII and IX. Therefore, Groups IV-VII and IX have different issues regarding patentability and enablement and represent patentably distinct subject matter.

7. If Applicant argues that inventions VI and VIII are somehow related as product and process of use, the inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product of (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case (2) the product as claimed can be made by synthetic organic chemistry or by screening on an array or by molecular modeling.

8. Furthermore, if applicant were to argue that any of the Groups I and IV-VII were somehow related as product and process of use, the inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product(s) as claimed (i.e., Groups I) can be used in materially different process of using that product (MPEP § 806.05(h)), for example, the products (i.e., Groups I) could be used with the methods in Groups IV-VII.

9. These inventions have acquired a separate status in the art as shown by their different classification and/or divergent subject matter. The different methods and products would require completely different searches in both the patent and non-patent databases, and there is no expectation that the searches would be coextensive. Therefore, this does create an undue search burden, and restriction for examination purposes as indicated is proper.

Species Election

10. This application contains claims directed to patentably distinct species of the claimed invention for Groups I-X. Election is required as follows.

11. If applicant elects the invention of Group I, applicant is required to elect from the following patentably distinct species. Claim 1 is generic.

Subgroup 1: Species of scaffold-based compound (see claim 1)

Applicant must elect for purposes of search a ***single species*** of scaffold-based compound. Furthermore, applicant must show ***all*** atoms and bonds that are necessary to define said scaffold-based compound. Applicant should NOT use general notations like R^1, R^2, R^3, R^4, etc. when defining the structure because these labels represent more than one chemical group and thus more than one compound would be erroneously elected. Please note that this "species" election is in addition to the "ring structure" requirements mentioned above.

12. If applicant elects the invention of Group II, applicant is required to elect from the following patentably distinct species. Claim 12 is generic.

Subgroup 1: Species of library (see claim 12)

Applicant is required to elect, for purposes of a search, a single specific library of compounds e.g., wherein all of the atoms and bond of a "representative" member is defined. The election should result in a ***particularly defined*** core structure that is shared by all library members. In defining this core structure, all variable groups should be defined (i.e. all atoms and bonds shown) as much as possible. However, if no common core structure exists, a representative example of the library must be elected. Please note that this "species" election is in addition to the "ring structure" requirements mentioned above.

13. If applicant elects the invention of Group III, applicant is required to elect from the following patentably distinct species. Claim 16 is generic.

Subgroup 1: Species of scaffold-based compound (see claim 16)

Applicant must elect for purposes of search a ***single species*** of scaffold-based compound. Furthermore, applicant must show ***all*** atoms and bonds that are necessary to define said scaffold-based compound. Applicant should NOT use general notations like R^1, R^2, R^3, R^4, etc. when defining the structure because these labels represent more than one chemical group and thus more than one compound would be erroneously elected. Please note that this "species" election is in addition to the "ring structure" requirements mentioned above.

Subgroup 2: Species of carrier (see claim 16)

Applicant must elect, for the purposes of search, a ***single species*** of carrier e.g., capsule w/ lactose.

Subgroup 3: Species of disease and cell activity (see claim 17)

Applicant must elect, for the purposes of search, a ***single species*** of disease and cell activity e.g., cancer w/ proliferation.

Subgroup 4: Species of use (e.g., see claim 18)

Applicant must elect, for the purposes of search, a ***single species*** of use e.g., veterinary.

14. If applicant elects the invention of Group IV, applicant is required to elect from the following patentably distinct species. Claim 22 is generic.

Subgroup 1: Species of scaffold-based compound (see claim 22)

Applicant must elect for purposes of search a ***single species*** of scaffold-based compound. Furthermore, applicant must show ***all*** atoms and bonds that are necessary to define said scaffold-based compound. Applicant should NOT use general notations like R^1, R^2, R^3, R^4, etc. when defining the structure because these labels represent more than one chemical group and thus more than one compound would be erroneously elected. Please note that this "species" election is in addition to the "ring structure" requirements mentioned above.

Subgroup 2: Species of cell activity (see claim 22)

Applicant must elect, for the purposes of search, a ***single species*** of cell activity e.g., proliferation.

Subgroup 3: Species of peptide or protein (e.g., see claim 22)

Applicant must elect, for the purposes of search, a ***single species*** of peptide or protein.

15. If applicant elects the invention of Group V, applicant is required to elect from the following patentably distinct species. Claim 23 is generic.

Subgroup 1: Species of scaffold-based compound (see claim 23)

Applicant must elect for purposes of search a ***single species*** of scaffold-based compound. Furthermore, applicant must show ***all*** atoms and bonds that are necessary to define said scaffold-based compound. Applicant should NOT use general notations like R^1, R^2, R^3, R^4, etc. when defining the structure because these labels represent more than one chemical group and thus more than one compound would be erroneously elected. Please note that this "species" election is in addition to the "ring structure" requirements mentioned above.

Subgroup 2: Species of cell activity (see claim 24)

Applicant must elect, for the purposes of search, a ***single species*** of cell activity e.g., proliferation.

Subgroup 3: Species of peptide or protein (e.g., see claim 24)

Applicant must elect, for the purposes of search, a ***single species*** of peptide or protein.

Subgroup 4: Species of disease (see claim 24)

Applicant must elect, for the purposes of search, a ***single species*** of disease.

16. If applicant elects the invention of Group VI, applicant is required to elect from the following patentably distinct species. Claim 25 is generic.

Subgroup 1: Species of library (see claim 25)

Applicant is required to elect, for purposes of a search, a single specific library of compounds e.g., wherein all of the atoms and bond of a "representative" member is defined. The election should result in a ***particularly defined*** core structure that is shared by all library members. In defining this core structure, all variable groups should be defined (i.e. all atoms and bonds shown) as much as possible. However, if no common core structure exists, a representative example of the library must be elected. Please note that this "species" election is in addition to the "ring structure" requirements mentioned above.

Subgroup 2: Species of differences (see claim 25)

Applicant must elect, for the purposes of search, a ***single species*** of differences e.g., chirality of pharmacophor.

Subgroup 3: Species of peptide or protein (e.g., see claim 25)

Applicant must elect, for the purposes of search, a ***single species*** of peptide or protein.

Subgroup 4: Species of activity (see claim 27)

Applicant must elect, for the purposes of search, a ***single species*** of activity e.g., proliferation.

17. If applicant elects the invention of Group VII or IX, applicant is required to elect from the following patentably distinct species. Claim 26 is generic for Group VII and claim 31 is generic for Group IX.

Subgroup 1: Species of library (see claim 26)

Applicant is required to elect, for purposes of a search, a single specific library of compounds e.g., wherein all of the atoms and bond of a "representative" member is defined. The election should result in a ***particularly defined*** core structure that is shared by all library members. In defining this core structure, all variable groups should be defined (i.e. all atoms and bonds shown) as much as possible. However, if no common core structure exists, a representative example of the library must be elected. Please note that this "species" election is in addition to the "ring structure" requirements mentioned above.

Subgroup 2: Species of differences (see claim 26)

Applicant must elect, for the purposes of search, a ***single species*** of differences e.g., chirality of pharmacophor.

Subgroup 3: Species of peptide or protein (e.g., see claim 26)

Applicant must elect, for the purposes of search, a ***single species*** of peptide or protein.

Subgroup 4: Species of activity (see claim 27)

Applicant must elect, for the purposes of search, a ***single species*** of activity e.g., proliferation.

18. If applicant elects the invention of Group VIII, applicant is required to elect from the following patentably distinct species. Claim 30 is generic.

Subgroup 1: Species of modulator (see claim 23)

Applicant must elect for purposes of search a ***single species*** of modulator. Furthermore, applicant must show ***all*** atoms and bonds that are necessary to define said modulator. Applicant should NOT use general notations like R^1, R^2, R^3, R^4, etc. when defining the structure because these labels represent more than one chemical group and thus more than one compound would be erroneously elected. Please note that this "species" election is in addition to the "ring structure" requirements mentioned above.

19. If applicant elects the invention of Group X, applicant is required to elect from the following patentably distinct species. Claim 32 is generic.

Subgroup 1: Species of marker linked compound (see claims 32-34)

Applicant must elect for purposes of search a ***single species*** of marker linked compound. Furthermore, applicant must show ***all*** atoms and bonds that are necessary to define said marker linked compound. Applicant should NOT use general notations like R^1, R^2, R^3, R^4, etc. when defining the structure because these labels represent more than one chemical group and thus more than one compound would be erroneously elected. Please note that this "species" election is in addition to the "ring structure" requirements

mentioned above. Furthermore, applicants must indicate which parts are the "linker" and the "marker" portions. Applicants must also indicate what the marker is used for (e.g., imaging) and what type of marker it is (e.g., radio-isotope).

20. **Please Note:** Applicants must disclose which claims read on the elected species (see paragraphs 24 and 25 below).

21. The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. For different species of method, the method steps for each species would differ. Moreover, the above species can be separately classified. Consequently, the species have different issues regarding patentability and represent patentably distinct subject matter. Therefore, this does create an undue search burden, and election for examination purposes as indicated is proper.

22. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

23. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance if the

examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a a rejection under 35 U.S.C. 103(a) of the other invention.

24. Applicant is advised that a reply to this requirement ***must include an identification of the species that is elected consonant with this requirement***, ***and a listing of all claims readable thereon, including any claims subsequently added***. An argument that a claim is allowable or that all claims are generic is considered ***nonresponsive*** unless accompanied by an election.

25. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, ***applicant must indicate which are readable upon the elected species***. MPEP § 809.02(a).

26. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.43). Because the above restriction/election requirement is complex, a telephone call to applicants to request an oral election was not made. See MPEP § 812.01.

27. Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

28. Applicant is also reminded that a 1 – month (not less than 30 days) shortened statutory period will be set for response when a written requirement is made without an action on the merits. This period may be extended under the provisions of 37 CFR 1.136(a). Such action will not be an "action on the merits" for purposes of the second action final program, see MPEP 809.02(a).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon D Epperson whose telephone number is (703) 308-2423. The examiner can normally be reached Monday through Friday from 8:30 a.m. to 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached on (703) 306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-2439.

Jon D. Epperson, Ph.D.
September 24, 2003

BENNETT CELSA
PRIMARY EXAMINER